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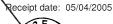
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: M. Rigdon Lentz

Serial No.: \$9/709,045 Art Unit: 1647

Filed: November 10, 2000 Examiner: Lorraine Spector

For: METHOD AND SYSTEM TO REMOVE CYTOKINE INHIBITOR IN PATIENTS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 27 C.F.R. §1.56, Applicants submit a

Supplemental Information Disclosure Statement, including fifteen (15) pages of Form PTO
1449, and copies of the one hundred and ninety-four (194) documents cited therein.

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. § 1.98. Applicants respectfully request consideration of this Information Disclosure Statement. The Commissioner is authorized to charge \$180.00, the fee set forth under 37 CFR § 1.17(p), to Account No. 50-3129 if necessary. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-3129.

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References duplicative of those cited or the IDS form itself. /CMW/

Class/Subclass

U.S. Patent Applications

Number	Publication Date	Inventor
2001/0010818	08-02-2001	Engle, et al.
2001/0039392	11-08-2001	Strahilevitz
2002/0019603	02-14-2002	Strahilevitz
2002/005803	05-16-2002	Tung, et al.
2002/0086276	07-04-2002	Srivastava
2002/0107469	08-08-2002	Bolan, et al.
2002/0111577	08-15-2002	Sirimanne, et al.
2002/0119147	08-29-2002	Howell, et al.
2002/0159995	19-31-2002	Brady, et al.
2002/0183677	12-05-2002	Chang, et al.
2002/0187069	12-12\2002	Levin, et al.
2002/0197249	12-26-2002	Brady, et al.
2002/0197250	12-26-2002	Brady, et al.
2002/0197251	12-26-2002	Brady, et al.
2003/0073822	04-17-2003	Mofling, et al.
2003/0118584	06-26-2003	Glenn, et al.
2003/0125657	07-03-2003 X	Koll, et al.
2003/0127390	07-10-2003	Davis, Jr.
2003/0133929	07-17-2003	Cham
2003/0138349	07-24-2003	Robinson, et al.
2003/0148404	08-07-2093	Michaelson
2003/0163077	08-28-2003	Kim, et al.
2003/0195452	10-16-2003	Hunley, exal.
2003/0215443	11 🕊 0-2003	Coffey, et a
2004/0044301	08-04-2004	Levin, et al.
2004/0054315	03-18-2004	Levin, et al.
/		

U.S. Patents

	Number /	Issue Date	<u>Patentee</u>
	4,116,589	09-26-1978	Rishton
	4,189,4 7 0	02-19-1980	Rose
	4,191,182	03-04-1980	Popovich, et al.
	4,3 5 0,156	09-21-1982	Malchesky, et al.
	4/362,155	12-07-1982	Skurkovich
	4,375,414	03-01-1983	Strahilevitz
/	4,581,010	04-08-1986	Skurkovich, et al.
	4,605,394	08-12-1986	Skurkovich
	4,620,977	11-04-1986	Strahilevitz

Class/Subclass

604/6.04

U.S.S.N.: 09/709,045
Filed: November 10, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

\	
4.633.417	12-30-1986
4,634,417	01-06-1987
4,604,913	05-12-1987
4,801,449	01-31-1989
4,813,924	03-21-1989
4,824,432	04-25-1989
4,834,973	05-30-1989
4,865,841	09-12-1989
4,963,265	10-16-1990
5,037,645	08-06-1991
5,037,649	08-06-1991
5,078,673	01-07-1992
5,356,374	10-18-1994
5,605,690	02-25 1997
5,626,843	05-06-1997
5,643,732	07-01-1997
5,705,615	01-06-1998
5,730,713	03-24-1998
5,753,227	05-19-1998 11-24-1998
5,840,588 5,869,047	02-09-1999
5,888,511	03-30-1999
5,910,252	06-08-1999
6,039,946	03-21-2000
6,197,289	03-06-2001
6,221,614	04-24-2001
6,245,038	06-12-2001
6,264,623	07-24-2001
6,287,516	09-11-2001
6,428,790	08-06-2002
6,432,405	08-13-2002
6,528,057	03-04-2003
6,561,997	05-13-2003
6,569,112	05-27-2003
6,602,592	08-05-2003
6,602,993	08-05-2003
6,697,501	08-19-2003
6,607,723 6,627,151	08-19-2003 09-30-2003
6,630,315	10-07-2003
6,676,622	01-13-2004
6,685,664	02-03-2004
-,000,001	02 03 2004

Wilburn, et al. Korec Mielke, et al. Balint, Jr., et al. Strahilevitz Skurkovich, et al. Strahilevitz Balint, Jr., et al. Okarma, et al. Strahilevitz Balint, Jr., et al Abrams Hogan, et al Jacobs, et/al. Skurkovich, et al. Strahnlevitz Lind, et al. Økarma, et al. Strahilevitz Strahilevitz Blake Kurkovich, et al. Truitt, et al. StrahNevitz Wirt, et al. Prusiner, et al. Borberg, et a Strahilevitz Matson, et al. Bovd Weinberg, et al. Ambrus, et al. Weitzel, et al. Strahilevitz Strahilevitz Wallach, et al. Gorsuch Good, et al. Borberg, et al.

> Miwa, et al. Strahilevitz Levin, et al.

leceipt date: 05/04/2005

U.S.S.N.: 09/709,045 Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

RE 31,688	09-25-1984	Popovich, et al.
RX 36,755	06-27-2000	Smith, et al.

Foreign Documents

Number	Publication Date	Patentee	Country
3302384	01-25-1983	Lysaght, et al.	DE
0076665	01-14-1987	E.I. Du Pont De Neptours	EP
	\	and Company	
2136314	09-19-1984	Gelman Sciences, Inc.	GB
56092824	0√- 27-1981	Terumo Corporation	JP
WO 79/01121	12 -2 7-1979	The Government of the	PCT
		United States of America	

Publications

ABBRUZZESE, et al., "A phase II that of recombinant human interferon-gamma and recombinant tumor necrosis factor in patients with divanced gastrointestinal malignancies: Results of a trial terminated by excessive toxicity. Journal of Biological Response Modifiers 9:522-527 (1990).

ADOLF AND APFLER, "A monoclonal antibody-based enzyme immunoassay for quantitation of human tumor necrosis factor binding protein I, a soluble fragment of the 60kDa TNF receptor, in biological fluids" J. mmunol. Meth. 143: 187-136 (1991).

AJANI, et al., "Phase I and II studies of the combination of recombinant human interferon-γ and 5-fluorouracil in patients with advanced colorectal carcinoma" *Journal of Biological Response Modifiers* 8:140-146 (1989).

ALBERTINI, et al., "Limiting dilution analysis of lymphokine-activated killer cell precursor frequencies in peripheral blood lymphocytes of cancer patients receiving interleukin-2 therapy" Journal of Biological Response Modifiers 9:456-462 (1990).

AREND Inhibiting the effects of cytokines in human diseases" Adv. Int. Med. 40:365-394 (1995).

AVNER, et al., "Therapeutic murine monoclonal antibodies developed for individual cancer patients" *Journal of Biological Response Modifiers* 8:25-36 (1989).

BALCEWICZ-SABLINSKA, et al., "Pathogenic Mycobacterium tuberculosis evades apoptosis of host macrophages by release of TNF-R2, resulting in inactivation of TNF-α" J. mmunol. 161:2636-2641 (1998).

eceipt date: 05/04/2005

U.S.S.N.: 09/709,045
Filed: November 10, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

BALIKO, et al., "Th2 biased immune response in cases with active Mycobacterium tuberculoris infection and tuberculin anergy" FEMS Immunol. Med. Micro. 22:188-204 (1998)

BERNUDEZ AND CHAMPSI, "Infection with Mycobacterium avium induces production of interleukin-10 (IL-10), and administration of anti-IL-10 antibody is associated with enhanced resistance to infection in mice" Infect. Immun. 61:3093-3097 (1993).

BEUTLER AND CERAMI, "The biology of cachectin/TNF-A primary mediator of the host response" Ann. Rev. Immunol. 7:625-655 (1989).

BLAUER, et al., "Medulation of the antilisterial activity of human blood-derived macrophages by activating and deactivating cytokines" *J. Interferon Cytokine Res.* 15:105-114 (1995).

BOMAN, et al., "Phase I study of recombinant gamma-interferon (rIFN- γ)" Journal of Biological Response Modifiers 7:438-446 (1988).

BRUNTSCH, et al., "phase II study of recombinant human interferon- γ in metastatic renal cell carcinoma" *Journal of Biological Response Modifiers* 9:335-338 (1990).

BUKOWSKI, et al., "Phase I trail of cophquous infusion of recombinant interleukin-2 and intermittent recombinant interferon-o_{2a}. Clinical effects" *Journal of Biological Response Modifiers* 9:538-545 (1990).

CAULFIELD, et al., "Phase I1-16 trial of an anti- O_{03} monoclonal antibody in combination with interferon- α in patients with malignant metanoma" *Journal of Biological Response Modifiers* 9:319-328 (1990).

CHAMBRIER, et al., "formonal and metabolic effects of opronic interleukin-2 infusion in cancer patients" *Journal of Biological Response Modifiers* 9:251-255 (1990).

CHOUAIB, et al, "More insights into the complex physiology of TNF" *Immunol. Today* 12(5):141-145 (1991)

COCLET-VININ, et al., "Interferon-beta not only inhibits interleukin-1 & and tumor necrosis factor- of but stimulates interleukin-1 receptor antagonist production in human peripheral blood mononyclear cells" Eur. Cytokine Network 8(4):345-349 (1997).

Coll.MAN, et al., <u>Hemostatsis and Thrombosis: Basic Principles and Clinical Practice</u>
2nd. Edition (Colman, et al., eds.) pp. 63-67 J.B. Lippincott: Philadelphia, PA, 1987.

COX, et al., "Phase II study of human lymphoblastoid interferon in patients with multiple psycloma" Journal of Biological Response Modifiers 7:318-325 (1988).

U.S.S.N.: 09/709,045 Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Receipt date: 05/04/2005

CREAVEN, et al., "Initial clinical trial of the macrophage activator muramyl tripeptide phosphandylethanolamine encapsulated in liposomes in patients with advanced cancer" Journal of Biological Response Modifiers 9:492-498 (1990).

CROGHAN, et al., "A phase I trial of recombinant interferon-α and α-difluoromethylomithine in metastatic melanoma" *Journal of Biological Response Modifiers* 7:409-415 (1988).

D'ANDREA, et λ_1 , "Interleukin 10 (IL-10) inhibits human lymphycyte interferon γ production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells" *J. Exp. Med.* 178:104 \(\cdot\) 1048 (1993).

DIMERY, et al., "Recomminant interferon- γ in the treatment of recurrent nasopharyngeal carcinoma" *Journal of Biological Response Modifiers* 8:221-226 (1989).

DINARELLO, "Induction of interleukin-I and interleukin-I receptor antagonist" Sem. In Oncol. 24(no. 3, Suppl. 9):81-93 (1997).

DUPERE, et al., "Patterns of cytokine released by peripheral blood leukocytes of normal donors and cancer patients during interleukin-2 convation in vitro" Journal of Biological Response Modifiers 9:140-148 (1990).

ENGELHARDT, et al, "Biological response to intravenously administered endotoxin in patients with advanced cancer" *Journal of Biological Response Modifiers* 9:480-491 (1990)

ENGELMANN, et al., "Two Jumor necrosis factor-binding proteins purified from human urine" J. Biol. Chem. 265(3):1531-1536 (1990).

ERIKS AND EMERSON, "Temporal effect of tumor necros is factor alpha on murine macrophages infected with Mycobacterium avium" Infect. Immun. 63(6):2100-2106 (1997).

ETGES AND MULLER, "Progressive disease or protective immunity to *Leishmania* major infection: the result of a network of stimulatory and inhibitory interactions" *J. Mol. Med.* 76:372-390 (1998).

FAREED, et al., "Novel antigenic markers of human tumor regression" *Journal of Biological Response Modifiers* 7:11-23 (1988).

FAVROT, et al., "Functional and immunophenotypic modifications induced by interleukin-2 did not predict response to therapy in patients with renal cell carcinoma" Journal of Biological Response Modifiers 9:167-177 (1990).

FERNANDES AND BALDWIN, "Interleukin-10 downregulates protective immunity to Brucella abortus" Infect. Immun. 63:1130-1133 (1995).

eceipt date: 05/04/2005

U.S.S.N.: 09/709,045
Filed: November 10, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

FOON, et al., "A prospective randomized trial of α_{2B}-interferon/γ-interferon or the combination in advanced metastatic renal cell carcinoma" *Journal of Biological Response Modifiers* 3-640-545 (1988).

FROST et al., "Interleukin-6 induction by a muramyltripeptide derivative in cancer patients" Journal of Biological Response Modifiers 9:160-166 (1990).

GADDUCCI, at al., "Serum levels of soluble receptors for tumor necrosis factor (p55 and p75 sTNFr) in endometrial cancer." *Anticancer Res.* 16:3125-3128 (1996)

GILL, et al., "Interfeton-alpha maintenance therapy after cytotoxic chemotherapy for treatment of acquired immunotefficiency syndrome-related kaposi sarcoma" *Journal of Biological Response Modifiers* 9 \$12-516 (1990).

GREENBLATT, et al., "The type B receptor for tumor necrosis factor-alpha" *Blood* 80:1339-1346 (1992).

GUSTAVSON, et al., "Pharmacokinetics of teoeleukin (Recombinant human inteleukin-2) after intravenous or subcutaneous administration to patients with cancer" *Journal of Biological Response Modifiers* 8:440-449 (1989).

HANDZEL, et al., "Immunomodulation of "cell deficiency in humans by thymic humoral factor: from crude extract to synthetic thymic humoral factor-γ2" *Journal of Biological Response Modifiers* 9:269-278 (1990).

HANK, et al., "Depressed in *fitro* T cell responses concomitant with augmented interleukin-2 responses by lymphotytes from cancer patients following *in vivo* treatment with interleukin-2" *Journal of Biological Response Modifiers* 9:5-14 (1990).

HERCEND, et al., "Immunotherapy with lymphokine-activated natural killer cells and recombinant interleukin-2/A feasibility trial in metastatic renal cell cartinoma" *Journal of Biological Response Modifiers* 9:546-555 (1990).

HERRMANN, et al., "Stimulation of granulopoiesis in patients with malignancy by recombinant human granulocyte-macrophage colony-stimulating factor: Assessment of two routes of administration" *Journal of Biological Response Modifiers* 9:475-479 (1900).

HEBTLER, et al., "A phase I study of T101-ricin A chain immunotoxin in refrectory chronic lymphocytic leukemia" *Journal of Biological Response Modifiers* 7:97-113 (1988).

HIMMLER, et al., "Molecular cloning and expression of human and rat tumor necros factor receptor chain (p60) and its soluble derivative, tumor necrosis factor-binding protein" *INA and Cell Biol.* 9(10):705-715 (1990).

Receipt date: 05/04/2005

U.S.S.N.: 09/709,045
Filed: November 10, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

JACOBS, et al., "minimal antigenicity of intron A in human recipients demonstrated by three analytical methods" *Journal of Biological Response Modifiers* 7:447-456 (1988).

JAKOBSEN, et al., "Decreased antitoxic activities among children with clinical episodes of malaria" *Infact. Immun.* 66(4):1654-1659 (1998).

JAKSCHIES, et al., "Emergence and decay of the human Ms homology in cancer patients during and after interrepon-α therapy" *Journal of Biological Response Modifiers* 9:305-312 (1990).

KALMANTI, et al., Serum levels of tumor necrosis factor soluble interleukin 2 receptor as markers of disease activity and prognosis in childhood leukemia and lymphoma" *Int. J. Hematol.* 57:147-152 (1993).

KAUFMANN, et al., "T cells and cytokines in intracellular bacterial infections: experiences with *Mycobacterium bovis* BCG" *Ciba Fdn. Symp.* 195:123-132 (1995).

KELLOKUMPU-LEHTINEN, et al. "Recombinant interferon-o2a and vinblastine in advanced renal cell cancer: A clinical phase III study" *Journal of Biological Response Modifiers* 9:439-444 (1990).

KESSLER, "Adsorptive plasma treatment: Optimization of extracorporeal devices and systems" *Blood Purification* 11:150-157 (1993).

KHAZAELI, et al., "Initial evaluation of a human annunoglobulin M monoclonal antibody (HA-1A) in humans" Journal of Biological Response Modifiers 9:178-184 (1990).

KOLITZ, et al., "Phase I trial of recombinant interleukin 2 and cyclophosphamide: Augmentation of cellular immunity and T-cell mitogenic response with long term administration of rIL-2" Journal of Biological Response Modifiers 7:457-472 (1988)

KRIGEL, et al., "freatment of epidemic kaposi's sarcoma with a combination of interferon-alpha 2b and etoposide" Journal of Biological Response Modifiers 7:359-364 (1988).

LANTZ, eval., "Infusion of tumor necrosis factor (TNF) causes an increase in circulating TNF-binding protein in humans" *Cytokine* 2(6):402-406 (1990).

LASZLO, et al., "Phase I studies of recombinant interferon-γ" Journal of Biological Response Modifiers 9:185-193 (1990).

LAUCELLA, et al., "Papel de las citoquinas en la resistencia y patologia durante la infeccion con Trypanosoma cruzi" Revista Argentina de Microbiologia, 28:99-109 (1996).

eceipt date: 05/04/2005

U.S.S.N.: 09/709,045
Filed: November 10, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

LENTZ, et al., "Apheresis of low molecular weight protein fraction and the onset of labor" Journal of Clinical Apheresis 5:62-67 (1990).

LENTZ, "The phylogeny of oncology" Mol. Biother. 2:137-144 (1990).

LETTER O AND ROBERTS, "Regulation of immune responses by TGPβ" Ann. Rev. Immuno. 16:137-101 (1998).

LITTON, et al., 'Biological and clinical effects of the oral immunomodulator 3,6'Bis(2-piperidinoethoxy)acridinoethoxylacridin

LUCEY, et al., "Type 1 and type 2 cytokine dysregulation in human infectious, neoplastic, and inflammatory diseases" Clin. Micro. Rev. 9(4):552-562 (1996).

MAAS, et al., "Interleukin-2 in cancer treatment: disappointing or (still) promising? A review" Cancer Immunol. Immunother. 36:141-148 (1997).

MACA, "Inhibition of the growth of the wis lung carcinoma by indomethacin in conventional, nude, and beige mice" *Journal of Biological Response Modifiers* 9:568-580 (1990).

MARSHALL, et al., "Effects of countarin (12 benzopyrone) and cimetidine on peripheral blood lymphocytes, natural killer cells, and monocytes in patients with advanced malignancies" Journal of Biological Response Modifiers 8:62-69 (1989).

MARSHALL, et al., "Treatment of renal cell carcinome with daily low-dose alphainterferon" *Journal of Biological Response Modifiers* 8:453-461 (1989).

MILES, et al., "induction of soluble tumour necrosis factor receptors during treatment with interleukn-2" *Brit. J. Qancer* 66:1195-1199 (1992).

MITTELMAN et al., "Treatment of patients with advanced cancer using multiple longterm cultured lymph kine-activatied killer (LAK) cell infusions and recombinant human interleukin-2" Journal of Biological Response Modifiers 8:468-478 (1989).

MUSIANI, et al., "Effect of low doses of interleukin-2 injected perilymphabeally and peritumorally in patients with advanced primary head and neck squamous cell carcinoma" Journal of Biological Response Modifiers 8:571-578 (1989).

NEIDHART, "Phase I study of recombinant methionyl human consensus interferon methulFN-Con)" Journal of Biological Response Modifiers 7:240-248 (1988).

eceipt date: 05/04/2005

U.S.S.N.: 09/709,045 Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ORATZ, et al. "Induction of tumor-infiltrating lymphocytes in human malignant melanoma metastases by immunization to melanoma antigen vaccine" *Journal of Biological Response Modifiers* 8:355-358 (1989).

ORATZ) et al., "Antimelanoma monoclonal antibody-ricin A chain immuneconjugate (XMMME-001-RVA) plus cyclophosphamide in the treatment of metastatic malfgnant melanoma: Results of a phase II trial" *Journal of Biological Response Modifiers* 9:345-354 (1990).

PAIS, et al., "Pharmacokinetics of recombinant interleukin-2 in children with malignancies: A pediatric oncology group study" *Journal of Biological Response Modifiers* 9:517-521 (1990).

PAOLOZZI, et al., "Phase Arial of recombinant interledkin-2 and recombinant β-interferon in refractory neoplastic diseases" *Journal of Biological Response Modifiers* 8:122-139 (1989).

PEREZ, et al., "A phase I trial of recombinant Juman gamma interferon (IFN-94A) in patients with advanced malignancy" Journal of Biological Response Modifiers 7:309-317 (1988).

QUESADA, et al., "Recombinant interferon alpha and gamma in combination as treatment for tetastatic renal cell carcinoma," *Journal of Biological Response Modifiers* 7:234-239 (1988).

RABINOWITZ, et al., "Hemolytic anemia in a cance patient treated with recombinant interferon-7" Journal of Biological Response Modifiers 9:256-259 (1990).

REIMANN, et al., "Surpression of the immune response by micro-organisms" Scand. J. Immunol. 31:543-546 (1990).

RIFFKIN, et al., Defense against the immune barrage: helminth urvival strategies" Immunol. Cell Bio 74:64-574 (1996)

ROMANI et al., "T helper cell dichotomy to *Candida albicans*: implications for pathology" *Immunol. Res.* 14:148-162 (1995).

ROYENTHAL, et al., "The *in vitro* function of lymphocytes from 25 cancer patients receiving four to seven consecutive days of recombinant IL-2" *Journal of Biological Response Modifyer* 7:123-139 (1988).

RYBAK, et al., "Interferon therapy of relapsed and refractory hodgkin's disease: Candid leukemia group B study 8652" Journal of Biological Response Modifiers 9:1-4 (1990).

U.S.S.N.: 09/709,045 Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

- ARNA, et al., "Systemic administration of recombinant methionyl human interleudin-2 (Ala 123 to cancer patients: Clinical results" *Journal of Biological Response Modifiers B*:16-24 (1989).
- SARNA et al., "A pilot study of intralymphatic interleukin-2. II. Clinical and biological effects" *Journal & Biological Response Modifiers* 9:81-86 (1990).
- SARTHOU, e.a.l., "Prognostic value of anti-Plasmodium falciparum specific immunoglobulin G3, cyokines, and their soluble receptors in west African patients with severe malaria" Infect. Immun. 63(8):3271-3276 (1997).
- SATO, et al., "induction of bone formation in an adenoid cyclic carcinoma of the maxillary sinus by adoptive immunotherapy involving intra-arterial injection of lympholine-activated killer cells and recombinant interleukin-2 in combination with radiotherapy" *Journal of Biological Response Modifiers* 9:329 334 (1990).
- SCHAADT, et al., "Phase II study of recombinant human tumor necrosis factor in colorectal carcinoma" *Journal of Biological Response Modifiers* 9:247-250 (1990).
- SCHALL, et al., "molecular cloning and expression of a receptor for human tumor necrosis factor" *Cell* 61:361-370 (1990).
- SCHEITHAUER, et al., "Combined o-2C-interferon/VMCP polychemotherapy versus VMCP polychemotherapy a induction the apy in multiple myeloma: A prospective randomized trial" *Journal of Biological Response Modifiers* 8:109-115 (1989).
- SCHILLER, et al., "A phase I trial of interferon-α-2a plus cyclophosphamide, vincristine, prednisone, and doxorubicin" *Journal of Biological Response Modifiers* 8:252-261 (1989).
- SECKINGER, et al., Purification and biologic characterization of a specific tumor necrosis factor α inhibitor" J. Biol. Chem. 264(20):11966-11973 (1989)
- SEIGLER, et al, "Melanoma patient antibody responses to melanoma tumor-associated antigens defined by hurine monoclonal antibodies" *Journal of Biological Response Modifiers* 8:37-52 (1989).
- SHAU, et al., "A pilot study of intralymphatic interleukin-2. I. Cytotoxic and surface marker charges of peripheral blood lymphocytes" *Journal of Biological Response Modifiers* 9:71-80 (1990).
- SIDHU AND BOLLON, "Tumor necrosis factor activities and cancer therapy A perspective" *Pharmacol. Ther.* 57:79-128 (1993).

Receipt date: 05/04/2005

U.S.S.N.: 09/709,045
Filed: November 10, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

SIELING, et al., "Immunosuppressive roles for IL-10 and IL-4 in human infection" Immunol, 150(12):5501-5510 (1993).

SPRIGGS, "One step ahead of the game: Viral immunomodulatory molecules" Ann. Rev. Immunol. 14:101-130 (1996).

STEGER, et al., "Long-term remission in a patient with erythroleukema following interferon- α treatment," Journal of Biological Response Modifiers 8:351-354 (1989).

STEINMETZ, et al. "Phase I study of 24-hour continuous intravenous infusion of recombinant human tumor necrosis factor" *Journal of Biological Resionse Modifiers* 7:417-423 (1988).

SZNOL, et al., "A phase I study of high-dose interleukin-2 in combination with interferon α_{2b} " Journal of Biological Response Modifiers 9:529-537 (1990).

TRIGG, et al., "c-interferon therapy for lymphopoliferative disorders developing in two children following bone marrow transplants," *Journal of Biological Response Modifiers* 8:603-613 (1989).

TRINCHIERI, et al., "Cytokine cross-tal between phagocytic cells and lymphocytes: Relevance for differentiation/Activation of phagocytic cells and regulation of adaptive immunity" *J. Cell. Biochem.* 53:301-308 (1993).

TRUMP et al., "Interferon-α-n1 and continuous infusion vinblastine for treatment of advanced renal cell carcinoma" *Journal of Biological Response Modifiers* 9:108-111 (1990).

UMIEL, et al., "Recombinant interleukin-2-activated intracavitary lymphocytes: Phenotypic characteristics and effector function" *Journal of Biological Response Modifiers* 8:409-421 (1989).

VON HOFF, et al., "Phase II evaluation of recombinant γ-interferon in patients with advanced pancreatic carcinoma: A southwest oncology group study" *Journal of Biological Response Modifiers* 9:584-587 (1990).

WALSH, et al., "Phase I study of the combination of alpha-2 interferon and cisplatinum" Journal of Biological Response Modifiers 8:11-15 (1989).

WEIL-HILLMAN, et al., "Transient decrease in IL-2 responsive lymphocytes 2 hours after initiation of continuous IL-2 infusion in cancer patients" *Journal of Biological Response Modifiers* 7:424-437 (1988).

eceipt date: 05/04/2005

U.S.S.N.: 09/709,045 Filed: November 10, 2000 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

WHITEHEAD, et al., "A phase II trial of recombinant tumor necrosis factor in patients with metastatic colorectal adenocarcinoma: A southwest oncology group study" *Journal of Biological Response Modifiers* 9:588-591 (1990).

YELA VARTHI, et al., "Analysis of p60 and p80 tumor necrosis factor-alpha" American Journal of Pathology 143:1131-1141 (1993).

ZAMKOFF, e. al., "A Phase I trial of subcutaneously administered recombinant tumor necrosis factor to patients with advanced malignancy" *Journal of Biological Response Modifiers* 8:539-552 (1989).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or incombination.

Respectfully submitted,

Tiffany B. Salmon Reg. No. 55,589

Dated: April 29, 2005

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CENT & DES	Examiner Name	Lorraine Spector
Sheet 1 of 15	Attorney Docket Number	LEN 102

		-	U.S. PATENT DOCUM	MENTS	
Examiner Initials*	Cite No.	US Patent Document Number Kind Code ²	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		(if known)			
		4,116,589	Rishton	09-26-1978	
		4,189,470	Rose	02-19-1980	
		4,191,182	Popovich, et al.	03-04-1980	
		4,350,156	Malchesky, et al.	09-21-1982	
		4,362,155	Skurkovich	12-07-1982	
		4,375,414	Strahilevitz	03-01-1983	
		4,581,010	Skurkovich, et al.	04-08-1986	
		4,605,394	Skurkovich	08-12-1986	
		4,620,977	Strahilevitz	11-04-1986	
		4,633,417	Wilburn, et al.	12-30-1986	
		4,634,417	Korec	01-06-1987	
		4,664,913	Mielke, et al.	05-12-1987	
		4,801,449	Balint, Jr., et al.	01-31-1989	
		4,813,924	Strahilevitz	03-21-1989	

					OREIGN PATENT DOCUMENT			
Examiner Initials*	Cite No.		Foreign Patent Docum	ent	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	To
		Office.3	Number*	Kind Code ⁵ (if known)				
		DE	3302384		Lysaght, et al.	01-25-1983		
		EP	0076665		E.I. Du Pont De Nemours	01-14-1987		
		GB	2136314		Gelman Sciences, Inc.	09-19-1984		
		JP	56092824		Terumo Corporation	07-27-1981		Г
		PCT	WO 79/01121		The Government of the United States of America	12-27-1979		
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CENT & TRUST	Examiner Name	Lorraine Spector
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			U.S. PATENT DOCUM		
xaminer Initials*	Cite No.	US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
		4,824,432	Skurkovich, et al.	04-25-1989	
		4,834,973	Strahilevitz	05-30-1989	
		4,865,841	Balint, Jr., et al.	09-12-1989	
		4,963,265	Okarma, et al.	10-16-1990	-
		5,037,645	Strahilevitz	08-06-1991	
		5,037,649	Balint, Jr., et al.	08-06-1991	
		5,078,673	Abrams	01-07-1992	
		5,356,374	Hogan, et al.	10-18-1994	
		5,605,690	Jacobs, et al.	02-25-1997	
		5,626,843	Skurkovich, et al.	05-06-1997	
		5,643,732	Strahilevitz	07-01-1997	
		5,705,615	Lim, et al.	01-06-1998	
		5,730,713	Okarma, et al.	03-24-1998	
		5,753,227	Strahilevitz	05-19-1998	
		5,840,588	Strahilevitz	11-24-1998	
		5,869,047	Blake	02-09-1999	
		5,888,511	Skurkovich, et al.	03-30-1999	
		5,910,252	Truitt, et al.	06-08-1999	
		6,039,946	Strahilevitz	03-21-2000	
		6,197,289	Wirt, et al.	03-06-2001	
		6,221,614	Prusiner, et al.	04-24-2001	
		6,245,038	Borberg, et al.	06-12-2001	
		6,264,623	Strahilevitz	07-24-2001	
		6,287,516	Matson, et al.	09-11-2001	
		6,428,790	Boyd	08-06-2002	
		6,432,405	Weinberg, et al.	08-13-2002	
		6,528,057	Ambrus, et al.	03-04-2003	-
kaminer's gnature	T			Date Considered	

*EXAMINER; Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

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xaminer Initials*	No.1		of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
		6,561,997	Weitzel, et al.	05-13-2003	-
		6,569,112	Strahilevitz	05-27-2003	
		6,602,502	Strahilevitz	08-05-2003	
		6,602,993	Wallach, et al.	08-05-2003	
		6,607,501	Gorsuch	08-19-2003	
		6,607,723	Good, et al.	08-19-2003	
		6,627,151	Borberg, et al.	09-30-2003	
		6,630,315	Miwa, et al.	10-07-2003	
		6,676,622	Strahilevitz	01-13-2004	
		6,685,664	Levin, et al.	02-03-2004	
		RE 31,688	Popovich, et al.	09-25-1984	
		RE 36,755	Smith, et al.	06-27-2000	
		2001/0010818	Engle, et al.	08-02-2001	
		2001/0039392	Strahilevitz	11-08-2001	
		2002/0019603	Strahilevitz	02-14-2002	
		2002/0058031	Tung, et al.	05-16-2002	
		2002/0086276	Srivastava	07-04-2002	
		2002/0107469	Bolan, et al.	08-08-2002	
		2002/0111577	Sirimanne, et al.	08-15-2002	
		2002/0119147	Howell, et al.	08-29-2002	
		2002/0159995	Brady, et al.	10-31-2002	
		2002/0183677	Chang, et al.	12-05-2002	
		2002/0187069	Levin, et al.	12-12-2002	
		2002/0197249	Brady, et al.	12-26-2002	
		2002/0197250	Brady, et al.	12-26-2002	
		2002/0197251	Brady, et al.	12-26-2002	
		2003/0073822	Lofling, et al.	04-17-2003	
		2003/0118584	Glenn, et al.	06-26-2003	
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Initials*	No.1		of Cited Document	Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
		Number Kind Code ² (if known)						
	-	2003/0125657	Koll, et al.	07-03-2003				
		2003/0127390	Davis, Jr.	07-10-2003				
		2003/0133929	Cham	07-17-2003				
		2003/0138349	Robinson, et al.	07-24-2003				
		2003/0148404	Michaelson	08-07-2003				
		2003/0163077	Kim, et al.	08-28-2003				
		2003/0195452	Hunley, et al.	10-16-2003				
		2003/0215443	Coffey, et al.	11-20-2003				
_		2004/0044301	Levin, et al.	03-04-2004				
		2004/0054315	Levin, et al.	03-18-2004				
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		ABBRUZZESE, et al., "A phase II trial of recombinant human interferon-gamma and recombinant lumor necrosis factor in patients with advanced gastrointestinal malignancies: Results of a trial terminated by excessive toxicity" Journal of Biological Response Modifiers 9:522-527 (1990).	
		ADOLF AND APFLER, "A monoclonal antibody-based enzyme immunoassay for quantitation of human tumor necrosis factor binding protein I, a soluble fragment of the 60kDa TNF receptor, in biological fluids" J. Immunol. Meth. 143:127-136 (1991).	
		AJANI, et al., "Phase I and II studies of the combination of recombinant human interferon-y and 5- fluorouracil in patients with advanced colorectal carcinoma" <i>Journal of Biological Response</i> [Modifiers 8:140-146 (1989).	
		ALBERTINI, et al., "Limiting dilution analysis of lymphokine-activated killer cell precursor frequencies in peripheral blood lymphocytes of cancer patients receiving interieukin-2 therapy" Journal of Biological Response Modifiers 9:456-462 (1990).	
		AREND, "Inhibiting the effects of cytokines in human diseases" Adv. Int. Med. 40:365-394 (1995).	
		AVNER, et al., "Therapeutic murine monoclonal antibodies developed for individual cancer patients" Journal of Biological Response Modifiers 8:25-36 (1989).	
		BALCEWICZ-SABLINSKA, et al., "Pathogenic Mycobacterium tuberculosis evades apoptosis of home macrophages by release of TNF-R2, resulting in inactivation of TNF-a" J. Immunol. 161:2636- 2641 (1998).	
		BALIKO, et al., "Th2 biased immune response in cases with active Mycobacterium tuberculosis infection and tuberculin anergy" FEMS Immunol. Med. Micro. 22:188-204 (1998).	
		BERMUDEZ AND CHAMPSI, "Infection with Mycobacterium avium induces production of interleukin-10 (IL-10), and administration of anti-IL-10 antibody is associated with enhanced resistance to infection in mice" infect. Immun. 61:3093-3097 (1993).	
		BEUTLER AND CERAMI, "The biology of cachectin/TNF-A primary mediator of the host response" Ann. Rev. Immunol. 7:625-655 (1989).	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application

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activating and deactivating cytokines" <i>J. Interferon Cytokine Res.</i> 15:105-114 (1995). BOMAN, et al., "Phase I study of recombinant gamma-interferon (rIFN-γ)" <i>Journal of Biological Response Modifiers</i> 7:438-446 (1998). BRUNTSCH, et al., "phase II study of recombinant human interferon- γ in metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:335-338 (1990). BUKOWSKI, et al., "Phase II stail of continuous infusion of recombinant interleukin-2 and intermittent recombinant interferon-σ ₂₀ . Clinical effects" <i>Journal of Biological Response Modifiers</i> 9:538-345 (1990). CAULFIELD, et al., "Phase I1-lb trial of an anti-G ₂₃ monoclonal antibody in combination with interferon-σ in patients with malignant melanoma" <i>Journal of Biological Response Modifiers</i> 9:319-328 (1990). CHAMBRIER, et al., "Hormonal and metabolic effects of chronic interleukin-2 infusion in cancer patients" <i>Journal of Biological Response Modifiers</i> 9:251-255 (1990). CHOUAIB, et al., "More insights into the complex physiology of TNF" <i>Immunol. Today</i> 12(5):141-145 (1991). COCLET-NININ, et al., "Interferon-beta not only inhibits interleukin-1β and tumor necrosis factor-σ but stimulates interleukin-1 receptor antagonist production in human peripheral blood mononuclear cells" <i>Eur. Cytokine Network</i> 8(4):345-349 (1997). COLMAN, et al., "Hemostatsis and Thrombosis: Basic Principles and Clinical Practice 2nd. Edition (Colman, et al., eds.) pp. 63-67 J.B. Lippincott: Philadelphia, P.A., 1987. COX, et al., "Phase II study of human lymphoblastoid interferon in patients with multiple myeloma" <i>Journal of Biological Response Modifiers</i> 7:318-325 (1998).		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
Response Modifiers 7:438-446 (1988). BRUNTSCH, et al., "phase II study of recombinant human interferon-y in metastatic renal cell carcinoma" Journal of Biological Response Modifiers 9:335-338 (1990). BUKOWSKI, et al., "Phase I trail of continuous infusion of recombinant interleukin-2 and intermittent recombinant interferon-a ₂₈ . Clinical effects" Journal of Biological Response Modifiers 9:538-545 (1990). CAULFIELD, et al., "Phase II-lb trial of an anti-G _{D3} monoclonal antibody in combination with interferon-a in patients with malignant melanoma" Journal of Biological Response Modifiers 9:319-328 (1990). CHAMBRIER, et al., "Hormonal and metabolic effects of chronic interleukin-2 infusion in cancer patients" Journal of Biological Response Modifiers 9:251-255 (1990). CHOUAIB, et al., "More insights into the complex physiology of TNF" Immunol. Today 12(5):141-145 (1991). COCLET-NININ, et al., "Interferon-beta not only inhibits interleukin-1β and tumor necrosis factor-a but stimulates interleukin-1 receptor antagonist production in human peripheral blood mononuclear cells" Eur. Cytokine Network 8(4):345-349 (1997). COLMAN, et al., Hemostatsis and Thrombosis: Basic Principles and Clinical Practice 2nd. Edition (Colman, et al., eds.) pp. 63-67 J.B. Lippincott: Philadelphia, PA, 1987. COX, et al., "Phase II study of human lymphoblastoid interferon in patients with multiple myeloma" Journal of Biological Response Modifiers 7:318-325 (1988). CREAVEN, et al., "Initial clinical trial of the macrophage activator muramyl tripeptide-phosphatidylethanolamine encapsulated in liposomes in patients with advanced cancer" Journal of			
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/ 1.0° E)	Filing Date	November 10, 2000
TEM & TRUTH	First Named Inventor	M. Rigdon Lentz
	Group Art Unit	1647
ENT & TRACE	Examiner Name	Lorraine Spector
Sheet 7 of 15	Attorney Docket Number	LEN 102

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Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
		CROGHAN, et al., "A phase I trial of recombinant interferon-a and a-difluoromethylornithine in metastatic melanoma" Journal of Biological Response Modifiers 7:409-415 (1988).	
		D'ANDREA, et al., "Interfeukin 10 (IL-10) inhibits human lymphocyte interferon y production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells" <i>J. Exp. Med.</i> 178:1041-1048 (1993).	
		DIMERY, et al., "Recombinant interferon- y in the treatment of recurrent nasopharyngeal carcinoma" Journal of Biological Response Modifiers 8:221-226 (1989).	
		DINARELLO, "Induction of interleukin-I and interleukin-I receptor antagonist" Sem. In Oncol. 24(no. 3, Suppl. 9):81-93 (1997).	
		DUPERE, et al., "Patterns of cytokines released by peripheral blood leukocytes of normal donors and cancer patients during interleukin-2 activation in vitro" Journal of Biological Response Modifiers 9:140-148 (1990).	
		ENGELHARDT, et al, "Biological response to intravenously administered endotoxin in patients with advanced cancer" <i>Journal of Biological Response Modifiers</i> 9:480-491 (1990)	
		ENGELMANN, et al., "Two tumor necrosis factor-binding proteins purified from human urine" J. Biol. Chem. 265(3):1531-1536 (1990).	
		ERIKS AND EMERSON, "Temporal effect of tumor necrosis factor alpha on murine macrophages infected with Mycobacterium avium" Infect. Immun. 65(6):2100-2106 (1997).	
		ETGES AND MULLER, "Progressive disease or protective immunity to Leishmania major infection: the result of a network of stimulatory and inhibitory interactions" J. Mol. Med. 76:372-390 (1998).	
		FAREED, et al., "Novel antigenic markers of human tumor regression" Journal of Biological Response Modifiers 7:11-23 (1988).	
		FAVROT, et al., "Functional and immunophenotypic modifications induced by interleukin-2 did not predict response to therapy in patients with renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9: 167-177 (1990).	

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		FERNANDES AND BALDWIN, "Interleukin-10 downregulates protective immunity to <i>Brucella abortus</i> " Infect. Immun. 63:1130-1133 (1995).
		FOON, et al., "A prospective randomized trial of σ_{23} -interferonly-interferon or the combination in advanced metastatic renal cell carcinoma" Journal of Biological Response Modifiers 7:540-545 (1988).
		FROST, et al., "Interleukin-6 induction by a muramyltripeptide derivative in cancer patients" Journal of Biological Response Modifiers 9:160-166 (1990).
		GADDUCCI, et al., "Serum levels of soluble receptors for tumor necrosis factor (p55 and p75 sTNFr) in endometrial cancer" Anticancer Res. 16:3125-3128 (1996).
		GILL, et al., "Interferon-alpha maintenance therapy after cytotoxic chemotherapy for treatment of acquired immunodeficiency syndrome-related kaposi's sarcoma" Journal of Biological Response Modifiers 9:512-516 (1990).
		GREENBLATT, et al., "The type B receptor for tumor necrosis factor-alpha" Blood 80:1339-1346 (1992).
		GUSTAVSON, et al., "Pharmacokinetics of teceleukin (Recombinant human inteleukin-2) after intravenous or subcutaneous administration to patients with cancer" Journal of Biological Response Modifiers 8:440-449 (1989).
		HANDZEL, et al., "Immunomodulation of T cell deficiency in humans by thymic humoral factor: from crude extract to synthetic thymic humoral factor-y2" Journal of Biological Response Modifiers 9:269-278 (1990).
		HANK, et al., "Depressed <i>in vitro</i> T cell responses concomitant with augmented interleukin-2 responses by lymphocytes from cancer patients following <i>in vivo</i> treatment with interleukin-2" Journal of Biological Response Modifiers 9:5-14 (1990).
		HERCEND, et al., "Immunotherapy with lymphokine-activated natural killer cells and recombinant interleukin-2: A feasibility trial in metastatic renal cell carcinoma" Journal of Biological Response Modifiers 9:546-555 (1990).

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Group Art Unit	1647		
Examiner Name	Lorraine Spector		
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		HERRMANN, et al., "Stimulation of granulopoiesis in patients with malignancy by recombinant human granulocyte-macrophage colony-stimulating factor: Assessment of two routes of	
		administration" Journal of Biological Response Modifiers 9:475-479 (1990).	
		HERTLER, et al., "A phase I study of T101-ricin A chain immunotoxin in refractory chronic lymphocytic leukemia" <i>Journal of Biological Response Modifiers</i> 7:97-113 (1988).	
		HIMMLER, et al., "Molecular cloning and expression of human and rat tumor necrosis factor receptor chain (p60) and its soluble derivative, tumor necrosis factor-binding protein". DNA and Cell Biol. 9(10):705-715 (1990).	
		JACOBS, et al., "minimal antigenicity of intron A in human recipients demonstrated by three analytical methods" Journal of Biological Response Modifiers 7:447-456 (1988).	
		JAKOBSEN, et al., "Decreased antitoxic activities among children with clinical episodes of malaria" Infect. Immun. 66(4):1654-1659 (1998).	
		JAKSCHIES, et al., "Emergence and decay of the human Ms homolog in cancer patients during and after interferon-α therapy" Journal of Biological Response Modifiers 9:305-312 (1990).	
		KALMANTI, et al., "Serum levels of tumor necrosis factor soluble interleukin 2 receptor as markers of disease activity and prognosis in childhood leukemia and lymphoma" Int. J. Hematol. 57:147-152 (1993).	
		KAUFMANN, et al., "T cells and cytokines in intracellular bacterial infections: experiences with Mycobacterium bovis BCG" Ciba Fdn. Symp. 195:123-132 (1995).	
		KELLOKUMPU-LEHTINEN, et al., "Recombinant interferon-α2a and vinblastine in advanced renal cell cancer: A clinical phase I-II study" Journal of Biological Response Modifiers 9:439-444 (1990).	
		KESSLER, "Adsorptive plasma treatment: Optimization of extracorporeal devices and systems" Blood Purification 11:150-157 (1993).	
		KHAZAELI, et al., "Initial evaluation of a human immunoglobulin M monoclonal antibody (HA-1A) in humans" Journal of Biological Response Modifiers 9:178-184 (1990).	

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		KOLITZ, et al., "Phase I trial of recombinant interleukin-2 and cyclophosphamide: Augmentation of cellular immunity and T-cell mitogenic response with long term administration of rlL-2" Journal of Biological Response Modifiers 7:457-472 (1988).	
		KRIGEL, et al., "Treatment of epidemic kaposi's sarcoma with a combination of interferon-alpha 2b and etoposide" <i>Journal of Biological Response Modifiers</i> 7:359-364 (1988).	
		LANTZ, et al., "Infusion of tumor necrosis factor (TNF) causes an increase in circulating TNF- binding protein in humans" Cytokine 2(6):402-406 (1990).	
		LASZLO, et al., "Phase I studies of recombinant interferon-γ" Journal of Biological Response Modifiers 9:185-193 (1990).	
		LAUCELLA, et al., "Papel de las citoquinas en la resistencia y patologia durante la infeccion con Trypanosoma cruzi" Revista Argentina de Microbiologia, 28:99-109 (1996).	
		LENTZ, et al., "Apheresis of low molecular weight protein fraction and the onset of labor" Journal of Clinical Apheresis 5:62-67 (1990).	
		LENTZ, "The phylogeny of oncology" Mol. Biother. 2:137-144 (1990).	
		LETTERIO AND ROBERTS, "Regulation of immune responses by TGF-β" Ann. Rev. Immuno. 16:137-161 (1998).	
		LITTON, et al., "Biological and clinical effects of the oral immunomodulator 3,6'Bis(2- piperidinoethoxy)sardine trihydrochloride in patients with malignancy" <i>Journal of Biological</i> <i>Response Modifiers</i> 9:61-70 (1990).	
		LUCEY, et al., "Type 1 and type 2 cytokine dysregulation in human infectious, neoplastic, and inflammatory diseases" Clin. Micro. Rev. 9(4):532-562 (1996).	
		MAAS, et al., "Interleukin-2 in cancer treatment: disappointing or (still) promising? A review" Cancer Immunol. Immunother. 36:141-148 (1993).	

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10. E	Filing Date	November 10, 2000	
An. A	First Named Inventor	M. Rigdon Lentz	
A	Group Art Unit	1647	
TENT & TEMPORAL	Examiner Name	Lorraine Spector	
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		lymphocytes,	natural killer cells, an	d monocytes in patients with advan-	ced malignancies" Journal of
		Biological Re	sponse Modifiers 8:62	2-69 (1989).	,
		MARSHALL.	et al., "Treatment of re	enal cell carcinoma with daily low-do	ose alpha-interferon" Journal
			Response Modifiers 8		
			· ·		
				tumour necrosis factor receptors du	ring treatment with
		interleukn-2"	Brit. J. Cancer 66:119	95-1199 (1992).	
		MITTELMAN	et al "Treatment of	patients with advanced cancer using	a multiple long-term cultured
				cell infusions and recombinant huma	
			sponse Modifiers 8:46		an interleuxin-2 Journal of
-					
		MUSIANI, et	al., Effect of low dose	es of interleukin-2 injected perilymph	natically and peritumorally in
				ad and neck squamous cell carcinor	ma" Journal of Biological
		Response ivid	odifiers 8:571-578 (19	89).	
		NEIDHART,	*Phase I study of reco	mbinant methionyl human consensu	us interferon (r-metHuIFN-
				se Modifiers 7:240-248 (1988).	,
		,			
				nfiltrating lymphocytes in human ma	
				lanoma antigen vaccine" Journal of	Biological Response
		Modifiers 8:3	55-358 (1989).		
		ORATZ, et al	., "Antimelanoma mor	noclonal antibody-ricin A chain immu	unoconiugate (XMMME-001-
				e treatment of metastatic malignant	
				Response Modifiers 9:345-354 (199	
				<u> </u>	
				ecombinant interleukin-2 in children	
		pediatric once	alogy group study" Joi	urnal of Biological Response Modifie	ers 9:517-521 (1990).
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	09/709,045
[Lat 0 5]	Filing Date	November 10, 2000
\ [** _£ /	First Named Inventor	M. Rigdon Lentz
	Group Art Unit	1647
TENTA TRADE	Examiner Name	Lorraine Spector
Sheet 12 of 15	Attorney Docket Number	LEN 102

OTHER ART - NON PATENT LITERATURE DOCUMENTS

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published PAOLOZZI, et al., "Phase I trial of recombinant interleukin-2 and recombinant β-interferon in refractory neoplastic diseases" Journal of Biological Response Modifiers 8:122-139 (1989).

	PEREZ, et al., "A phase I trial of recombinant human gamma interferon (IFN- γ_{4A}) in patients with advanced malignancy" Journal of Biological Response Modifiers 7:309-317 (1988).
	QUESADA, et al., "Recombinant interferon alpha and gamma in combination as treatment for tetastatic renal cell carcinoma" Journal of Biological Response Modifiers 7:234-239 (1988).
	RABINOWITZ, et al., "Hemolytic anemia in a cancer patient treated with recombinant interferon-γ" Journal of Biological Response Modifiers 9:256-259 (1990).
	REIMANN, et al., "Suppression of the immune response by micro-organisms" Scand. J. Immunol. 31:543-546 (1990).
-6:-	RIFFKIN, et al., "Defense against the immune barrage: helminth survival strategies" Immunol. Cell Bio 74:564-574 (1996)
	ROMANI, et al., "T helper cell dichotomy to Candida albicans: implications for pathology" Immunol. Res. 14:148-162 (1995).
	ROSENTHAL, et al., "The <i>in vitro</i> function of lymphocytes from 25 cancer patients receiving four to seven consecutive days of recombinant IL-2" <i>Journal of Biological Response Modifiers</i> 7:123-139 (1988).
	RYBAK, et al., "Interferon therapy of relapsed and refractory hodgkin's disease: Cancer and leukemia group B study 8652" Journal of Biological Response Modifiers 9:1-4 (1990).
	SARNA, et al., "Systemic administration of recombinant methionyl human interleukin-2 (Ala 125) to cancer patients: Clinical results" Journal of Biological Response Modifiers 8:16-24 (1989).
	SARNA, et al., "A pilot study of intralymphatic interleukin-2. II. Clinical and biological effects" Journal of Biological Response Modifiers 9:81-86 (1990).
	SARTHOU, et al., "Prognostic value of anti-Plasmodium falciparum-specific immunoglobulin G3, cytokines, and their soluble receptors in west African patients with severe malaria" Infect. Immun. 65(8):3271-3276 (1997).
Examiner's Signature	Date Considered

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ι,	ENT & TRACEPACT		First Named Inventor	M. Rigdon Lentz
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~	ENT & TROUB		Examiner Name	Lorraine Spector
	Sheet 13 of	15	Attorney Docket Number	LEN 102

OTHER ART - NON PATENT LITERATURE DOCUMENTS.

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		SATO, et al., "induction of bone formation in an adenoid cystic carcinoma of the maxillary sinus by	
		adoptive immunotherapy involving intra-arterial injection of lympholine-activated killer cells and	
		recombinant interleukin-2 in combination with radiotherapy" Journal of Biological Response Modifiers 9:329-334 (1990).	
		SCHAADT, et al., "Phase II study of recombinant human tumor necrosis factor in colorectal	
		carcinoma" Journal of Biological Response Modifiers 9:247-250 (1990).	
		SCHALL, et al., "molecular cloning and expression of a receptor for human tumor necrosis factor" Ce/l 61:361-370 (1990).	
		SCHEITHAUER, et al., "Combined α-2C-interferon/VMCP polychemotherapy versus VMCP	
		polychemotherapy a induction therapy in multiple myeloma. A prospective randomized trial"	
		Journal of Biological Response Modifiers 8:109-115 (1989).	
		SCHILLER, et al., "A phase I trial of interferon-α-2a plus cyclophosphamide, vincristine,	
		prednisone, and doxorubicin" Journal of Biological Response Modifiers 8:252-261 (1989).	
		SECKINGER, et al., "Purification and biologic characterization of a specific tumor necrosis factor α inhibitor" <i>J. Biol. Chem.</i> 264(20):11966-11973 (1989).	
		SEIGLER, et al, "Melanoma patient antibody responses to melanoma tumor-associated antigens defined by murine monoclonal antibodies" Journal of Biological Response Modifiers 8:37-52 (1989).	
		SHAU, et al., "A pilot study of intralymphatic interleukin-2. I. Cytotoxic and surface marker changes of peripheral blood lymphocytes" Journal of Biological Response Modifiers 9:71-80 (1990).	
		SIDHU AND BOLLON, "Tumor necrosis factor activities and cancer therapy – A perspective" Pharmacol. Ther. 57:79-128 (1993).	
		SIELING, et al., "Immunosuppressive roles for IL-10 and IL-4 in human infection" <i>J. Immunol.</i> 150(12):5501-5510 (1993).	
		SPRIGGS, "One step ahead of the game: Viral immunomodulatory molecules" Ann. Rev. Immunol. 14:101-130 (1996).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	09/709,045	
14 E	Filing Date	November 10, 2000	
SENTATRACES	First Named Inventor	M. Rigdon Lentz	
Street and the street	Group Art Unit	1647	
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		STEGER, et al., "Long-term remission in a patient with erythroleukemia following interferon-a treatment" Journal of Biological Response Modifiers 8:351-354 (1989).	
		STEINMETZ, et al., "Phase I study of 24-hour continuous intravenous infusion of recombinant human tumor necrosis factor" Journal of Biological Response Modifiers 7:417-423 (1988).	
		SZNOL, et al., "A phase I study of high-dose interleukin-2 in combination with interferon a_{2b} " Journal of Biological Response Modifiers 9:529-537 (1990).	
		TRIGG, et al., "a-interferon therapy for lymphoproliferative disorders developing in two children following bone marrow transplants" Journal of Biological Response Modifiers 8:603-613 (1989).	
		TRINCHIERI, et al., "Cytokine cross-talk between phagocytic cells and lymphocytes: Relevance for differentiation/Activation of phagocytic cells and regulation of adaptive immunity" J. Cell. Biochem. 53:301-308 (1993).	
		TRUMP et al., "Interferon-a-n1 and continuous infusion vinblastine for treatment of advanced renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:108-111 (1990).	
		UMIEL, et al., "Recombinant interleukin-2-activated intracavitary lymphocytes: Phenotypic characteristics and effector function" Journal of Biological Response Modifiers 8:409-421 (1989).	
		VON HOFF, et al., "Phase II evaluation of recombinant γ-interferon in patients with advanced pancreatic carcinoma: A southwest oncology group study" Journal of Biological Response Modifiers 9:584-587 (1990).	
		WALSH, et al., "Phase I study of the combination of alpha-2 interferon and cisplatinum" Journal of Biological Response Modifiers 8:11-15 (1989).	
		WEIL-HILLMAN, et al., "Transient decrease in IL-2 responsive lymphocytes 24 hours after initiation of continuous IL-2 infusion in cancer patients" Journal of Biological Response Modifiers 7:424-437 (1998).	

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		WHITEHEAD, et al., "A phase II trial of recombinant tumor necrosis factor in patients with metastatic colorectal adenocarcinoma: A southwest oncology group study" Journal of Biological Response Modifiers 9:588-591 (1990).	
		YELAVARTHI, et al., "Analysis of p60 and p80 tumor necrosis factor-alpha" American Journal of Pathology 143:1131-1141 (1993).	
		ZAMKOFF, et al., "A Phase I trial of subcutaneously administered recombinant tumor necrosis factor to patients with advanced malignancy" <i>Journal of Biological Response Modifiers</i> 8:539-552 (1989).	
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Examiner's Signature	/Cherie M. Woodward/	Date Considered	11/08/2011	

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